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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

9

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 8-12 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 8-12, and 15-27 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks in Paper No. 8, filed 4/28/03, are acknowledged. Amended claim 5 and 8-12; new claims 15-27; and cancelled claims 1-4, 6-7, and 13-14 are acknowledged.

Applicant's arguments, filed 4/28/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, Figures 8 and 9. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks a paper copy, computer readable form, or CD-ROM and SEQ ID Nos cited along with each sequence in the Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification.

Applicant(s) are required to submit a computer readable form sequence listing, a paper copy, or CD-ROM for the specification, statements under 37 CFR § 1.821 (f) and (g). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Claims 5 (amended), 8-12 (amended), and 15-27 (new) are herein under examination.

Claim Objection

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 fails to further limit claim 15. Claim 16 is broader than claim 15 in that the source identification information is not described in the claim as being directed to the more narrow limitation of claim 15 for the identification of the genetic information in "said first portion". This objection is necessitated by amendment.

Claim Rejections – 35 USC § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

The rejection of claims 5 and 8-12 is maintained and newly applied to new claims 15-27 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicants argue that the claims recite sequences that are not naturally-occurring in DNA. While the claims include manmade DNA where the added nucleotide sequence distinguishes the claimed DNA from naturally occurring DNA, the claims as written also encompass sequences that are naturally occurring. It is reasonable to interpret the source identification information as a naturally occurring fragment as well as one designed by the hands of man. As stated in the previous action, in the absence of the hands of man, the naturally

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occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

Claims Rejected Under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

As no support was pointed to by Applicants and after reviewing the specification, no written support appears to exist for "is not operably-linked to said genetic information in first portion" as stated in claim 27. Because the introduction of "is not operably-linked to said genetic information in first portion" lacks written basis for new claim 27, as filed in Paper No. 8 on 4/28/03, it is considered NEW MATTER.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the phrase "provided by one of selective breeding, cultivation, and gene manipulation" which is vague and indefinite. If the provision is accomplished by "one" then it is unclear why "and" is used in this phrase. Clarification of whether all or just one of the provisions is required is needed. This rejection is necessitated by amendment.

Claim 24 recites the phrase "comprises one of a restrictive enzyme identification sequence and a promoter" is vague and indefinite. It is unclear if both the restrictive enzyme identification sequence and a promoter are required or if one of each is required. Clarification of this issue is requested. This rejection is necessitated by amendment.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5 and 8-12 is maintained and newly applied to claims 15-21 and 24-26 under 35 U.S.C. 102(b) as being anticipated by Oliver et al. (P/N 5,723,765).

The rejection from Paper No. 7, mailed 1/27/03, is reiterated and maintained for reasons of record.

Applicants state on page 7, second paragraph of Paper No. 8 (filed 4/28/03), the Oliver et al. reference discloses the addition of DNA whose expression results in phenotypic alterations that are linked to the promoter. Applicants state Oliver et al. disclose making a modified hybrid plant. This is acknowledged. Applicants continue to state on page 7, third paragraph, that Oliver does not teach or suggest "a nucleotide sequence which is added to said portion including no genetic information, and comprises source identification information for identifying a source of said genetic information in said gene portion" as stated in instant claims 5 and 12 and similarly stated in instant claim 8. This is found unpersuasive. As the definition of genetic information is not described by Applicants, one reasonable interpretation of genetic information is information that provides the characteristic genetic background of an organism or group of organisms, whereas the promoter is involved in expression control information. Therefore, the presence of the added promoter fulfills this requirement which can serve as identification of the gene which is not part of the genetic information that is included in the genetic heritage of an organism (see "source identification information" discussion below). Applicants further discuss the use of their invention to identify the source of genetic information when it is copied by a third party and prevents illegal copying. The Examiner agrees that this material is indeed distinguishable from the prior art reference; however, these limitations are not set forth in the claims. The claims, as written, are broadly interpreted to encompass the invention of Oliver et al. Applicants mention

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that Oliver et al. disclose a method wherein a gene is operably-linked to a transiently active promoter whereas the claimed invention does not include this feature. First, it is unclear where Applicants claim written support for the idea of the DNA not being allowed to be operably-linked to any part of the genetic information as stated on page 8, first paragraph of Paper No. 8 (filed 4/28/03) and in instant claim 27. Furthermore, this characterization only applies to instant claim 27 (which is dependent from instant claim 15) which means the other claims (including instant claim 15 by itself) do not have this limitation. Applicants state on page 8, second and third paragraphs, that they mention the differences between Oliver et al. and their invention in the specification. As stated above, these differences do not appear in all of the claims as written. Applicants disagree with the interpretation of the promoter serving as a "source identification information." The mere presence of the specific promoter inherently provides identification to the gene. As the term "source" is very broad including definitions "a point of origin" and "one that supplies information" (from the online Merriam Webster dictionary), the promoter indeed supplies information merely because a specific promoter was used. Applicants continue to state on page 9, first paragraph through page 10, third paragraph, various differences between what they feel is their invention and differences from the Oliver et al. invention. This is found unpersuasive because, as mentioned above, the claims as written are broadly interpreted to encompass the invention of Oliver et al. Because these differences stated by Applicants are not stated in the claims (especially the independent claims), the majority of the claims are not distinguished in their broadest reasonable interpretation from the Oliver et al. reference.

The rejection of the new claims 15-21 and 24-26 is described below. As stated in the previous Office action, Oliver et al. disclose sequences that can be introduced into a plant (col. 2,

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lines 25-27) so that a recombinase gene (a gene portion) and a promoter (a portion containing no genetic information) are present in the DNA (col. 2, lines 41-42) as stated in instant claim 15.

Oliver et al. disclose that the promoter can be from viral, bacterial, fungal, animal, or plant origin (col. 4, lines 5-7). The "source identification information" is reasonably interpreted to mean information identifying a particular gene. As Oliver et al. disclose a Lea promoter containing a specific known sequence (see Example 2, col. 9, lines 50-67, where specific primers were made on either side of the promoter sequence), this promoter is inherently correlated with information pertaining to the gene transmitting genetic information as stated in instant claim 5, because the gene and promoter are considered to be operably linked on the same strand of DNA (col. 4, lines 17-18).

Oliver et al. disclose DNA with promoter sequences correlated with "source identification information" (see previous paragraph) where the gene is expressed when a "transiently-active promoter becomes active in the normal course of growth and development" (col. 2, lines 46-51 and col. 4, lines 1-4), which is reasonably interpreted to mean that the promoter does not affect the regular transmission of genetic information by the gene as stated in instant claim 18. As "special sequence" is undefined in the specification, it is reasonably interpreted to mean any selected sequence.

Oliver et al. disclose DNA sequences being transfected into plant cells (abstract) which is a form of gene manipulation as stated in instant claim 17. Oliver et al. disclose that the plant cell is transfected with DNA sequences comprising multiple genes (gene portions) and multiple promoters (portions containing no genetic information) which are different from each other (abstract) as required in instant claims 19 and 20. Oliver et al. disclose regenerating a whole

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plant from a plant cell (abstract) which is reasonably interpreted to mean that the sequences involved were tolerably copied as required in instant claim 21. Oliver et al. disclose a nucleotide sequence having promoter fragments and fragments cut by particular restriction enzymes (col. 10, lines 41-57) which thereby identifies the enzymes due to having the sequences required by the enzymes required in instant claim 24. Oliver et al. disclose nucleotide sequences (abstract) while any nucleotide sequence is detectable via complementary sequence probes as stated in instant claim 25.

Oliver et al. disclose introducing a series of functionally interrelated DNA sequences, containing promoters and genes (col. 2, lines 65-67 and col. 3, lines 1-41). As each promoter may include a specific sequence with a specific nucleotide assembly pattern, this is reasonably interpreted as the presence of several of these sequences to represent the "multiple types of patterns". Oliver et al. disclose the promoters, or "special sequence[s]" in this case, are located in predetermined locations of DNA as stated in instant claim 26, as seen in Example 5 (col. 12, lines 40-45) where a 35S promoter was isolated and subcloned back into pMM23 to yield pMM23tet30, where the coding sequence was flanked by the promoter. Oliver et al. disclose this construct being introduced into cotton cells (col. 14, lines 7-10). Thus, Oliver et al. anticipate the limitations in claims 5, 8-12, 15-21, and 24-26 of the instant invention.

The reiteration or disclosure of new sections within the prior art reference was mentioned as necessitated by amendment by the addition of new claims 15-21 and 24-26.

Conclusion

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

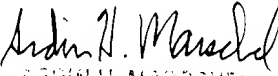
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 9, 2003


ARDIN H. MARSCHEL
ATTORNEY AT LAW